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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,796	01/11/2002	Naida M. Loskutoff	13511.1USU1	8344

23552 7590 10/29/2004

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,796	LOSKUTOFF ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6,8-14,21,22 and 24-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6,8-14,21,22 and 24-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Official translation of EP685,576 and reference by Hellemann.

DETAILED ACTION

Claims 1, 2, 4-6, 8-14, 21, 22 as amended and new claims 24-32 (filed on 8/16/2004) are pending and under examination in the instant office action.

Claims 3, 7, 15-20 and 23 were canceled by applicants (8/16/2004).

Claim Rejections - 35 USC § 112

Indefinite

New claims 24, 25, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New claims 24, 25, 28 and 29 are rendered indefinite by term "IU" because it is unclear what are amounts or weight units that are encompassed by this term in order to estimate concentrations of antioxidant(s) in the claimed composition. Thus, concentrations as claimed are uncertain and indefinite.

New matter

New claims 25 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation drawn to the antioxidant concentration range from "about 1 IU/ml to about 5 IU/ml" has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by

way of generic disclosure of the range from 1 IU/ml to 5 IU/ml, nor are there specific examples of the newly limited genus that would show possession of the concept of the use of the antioxidant concentration range from 1 IU/ml to about 5 IU/ml.

The generic disclosure teaches that antioxidant concentration can be at least 5 IU/ml and more (specification page 7, line 13). This is a range different from the presently claimed range since it is not limited by the highest value of 5 IU/ml as presently claimed. Furthermore, some of examples demonstrate the use of 10 IU/ml of antioxidant or 10 IU/ml of vitamin E (page 19, last lines in tables 8 and 9).

Thus, there is no sufficient support for the new limitation or newly inserted concentration range. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the limitation drawn to antioxidant concentration range from "about 1 IU/ml to about 5 IU/ml" is considered to be the insertion of new matter for the above reasons.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 6, 8, 11-14, 21, 22 as amended and new claims 27 and 32 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 685 556 [IDS reference] for the reasons as explained in the prior office action and repeated herein.

Claims are directed to a semen extender composition that is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin, surfactant, carbohydrate and buffer to provide for pH of about 6.9-7.2 and osmolarity of about 250-350 mOsm. Some claims are further drawn to the use of 90% water in the composition, to the use of 0.1-6.0% of non-animal derived phospholipid in the composition, to the use of freeze agent or glycerol at concentration 3-14% in the composition. Some claims are further drawn to incorporation of semen into the semen extender composition. Some claims are/are further drawn to the method of making the semen extender composition by mixing the components of the composition. Some claims are further drawn to the use of 0.0001-1% of surfactant in the composition.

EP 0 685 556 discloses a semen extender composition which is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin, a mixture of Tris and sodium citrate which act as both surfactant and buffer, carbohydrate such as glucose, fructose or lactose and freeze agent or glycerol (see page 3, lines 4-16). The amounts or concentrations of ingredients in the cited semen extender composition are within the ranges of the claimed semen extender composition. Although the cited patent is silent with regard to pH and osmolarity of the semen extender composition and/or solution for semen preservation, the values of pH and osmolarity that are claimed are regular parameters that are commonly used for animal cell culture maintenance and preservation. The cited EP patent also teaches the method of making the semen extender composition by mixing the components of the composition. The cited EP patent also teaches incorporation of semen into the semen extender

composition (example 3). Thus, the cited patent EP 0 685 556 anticipates the presently claimed invention.

Claims 1, 2, 4-6, 8, 10-14, 21, 22 as amended and new claims 27 and 32 remain/are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,368,786 for the reasons as explained in the prior office action and repeated herein.

Claims 1-3, 6, 7, 8, 11-14 and 21-23 as explained above. Claims 4 and 5 are further drawn to incorporation of antioxidant or vitamin A into the semen extender composition. Claim 10 is further drawn to incorporation of polyoxyethylene sorbitan (Tween 80) into the semen extender composition. Some claims are further drawn to the use of 0.0001-1% of surfactant in the composition.

US 6,368,786 teaches a semen extender composition that is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin, surfactant, carbohydrate and buffer to provide for pH of about 6.9-7.2 and osmolarity of about 250-350 mOsm, for example: the diluent compositions as disclosed in the tables at col. 3 and 4. The amounts and /or concentrations of ingredients in the cited semen extender composition are within the ranges of the claimed semen extender composition. At least one diluent composition is identical to the composition of the cited above EP 0 685 556 (see example 4 of US'786). Further, the diluent composition of the US'786 comprises antioxidant or vitamin A dissolved in emulsifier (surfactant) such as Tween 80 (col. 1, lines 49-56). The cited US'786 also teaches the method of making the semen extender composition by mixing the components of the

composition. The cited US patent also teaches incorporation of semen into the semen extender composition (example 3).

Thus, the cited patent US 6,368,786 anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-6, 8-14, 21, 22 as amended and new claims 24-32 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 685 556 [IDS reference] or US 6,368,786 [PTO form 892] taken with US 3,444,039 [IDS reference], US 6,130,034 [IDS reference], US 6,140,121 [IDS reference] and the reference by Hellmann et al. [1988, IDS reference 1] for the reasons as explained in the prior office action and repeated herein.

Claims 1, 2, 4-6, 8, 10-14, 21, 22, 27, 32 as explained above. Some claims are further drawn to the use of surfactant such as sodium lauryl sulfate, to the use of antioxidant such as vitamin E in the semen extender composition and to the use of specific concentrations of anti-oxidant(s).

EP 0 685 556 or US 6,368,786 are relied upon as explained above for the disclosure of semen extender compositions. They are lacking disclosure about the use of various surfactants and/or antioxidant vitamins.

However, the cited patent US 6,130,034 teaches incorporation of antioxidant such as vitamin E, for example: see col. 1, line 50, as a commonly used and/or regular component in the

composition intended for semen transportation and storage (col. 1, line 29). The suggested concentration for anti-oxidant vitamin E is 1mM (col. 1, line 54).

The reference by Hellmann et al. teaches incorporation of sodium lauryl sulfate into composition intended for animal semen preservation (see abstract).

In addition, US 3,444,039 is relied upon to demonstrate that sodium citrate buffering preparation provides for neutral pH of about 6 -7 and osmolarity of about 250-300 mOsm which are regular pH and osmolarity parameters commonly used for animal cell culture maintenance and preservation (see col. 2, line 6 or see col. 3, line 30 and 44). And the cited US 6,140,121 teaches incorporation of various buffers into compositions intended for semen preservation including buffers such as EDT (col. 19, line 28) or Tris or sodium citrate s well as polyoxyethylene sorbitan which is Tween 80 within the medium M199 in the composition intended for freezing sperm (col. 16, lines 57-59).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to incorporate ingredients such as various antioxidants and various surfactants into the semen extender composition as required by the presently claimed invention with a reasonable expectation of success in obtaining composition suitable for semen maintenance and/or preservation because these compositions and ingredients have been known and commonly used in the field of semen maintenance and preservation as adequately demonstrated by the cited references in combination. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 8/16/2004 have been fully considered but they are not persuasive.

With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by EP 0 685 556 {Ghazarian et al.} applicants argue that the cited composition is different from the presently claimed composition because the cited composition lacks the presently claimed component (b) that is "effective amount of surfactant to reduce ice crystal formation during freezing of the compositions" (response page 8). Applicants argue that Tris components in the cited composition is a buffer not a surfactant. However, although Tris (trimethylol methylamine) is widely used as a biological buffer, it also functions as a surfactant or "agent that alters physical or chemical properties of surfaces" since it is an alkalizer and an emulsifier according to Merck Index. Thus, the cited composition contains at least one agent that would function as a generic surfactant within the meaning of the claims. Besides, the cited reference teaches the use of sodium citrate as anticoagulant in the cited composition. Thus, sodium citrate would also function as surface-active agent. The presently claimed component (b) is a generic agent having a genetic function. The claimed component (b) is not necessarily one specific ingredient. The cited composition contains various agents that would functions as surfactants and that would also provide function such as "to reduce ice crystal formation during freezing", for example: glycerol, fructose, glucose, etc. Therefore, the cited composition contains the presently claimed generic component (b) having generic function(s). Thus, the cited composition is not different from the presently claimed composition.

With regard to the claim rejection under 35 U.S.C. 102(e) as being anticipated by US 6,368,786 {Saint-Ramon et al.} applicants argue that the cited patent fails to clearly indicate that the resulting composition has pH 6.9-75 and osmolarity 250-350 mOsm (response page 9). This is not found persuasive because the cited patent teaches the use of Tris-sodium citrate buffer that is known to provide for the same pH range as presently claimed. The cited composition is successfully used as a diluent for semen preservation, artificial insemination, etc. Thus, the cited composition is physiologically acceptable for biological applications. Therefore, there is a reasonably believe that osmolarity of the cited semen diluent composition is within normal physiologically acceptable range that is the same as the presently claimed osmolarity range between 250-350 mOsm.

With regard to US 6,368,786 {Saint-Ramon et al.} applicants also appears to argue the date of the reference. However, the effective filing date or the 102(e) date is May 11, 2000 that is before the applicants' effective filing date.

As related to claim rejection under 35 USC § 103 it is noted that in response to applicant's arguments against the references individually (response pages 10-11), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Although the secondary references US 3,444,039 {Rajamannan}, US 6,130,034 {Aitken} and Hellmann et al disclose compositions with animal-derived phospholipid component such as egg yolk but not soy lecithin as taught by the cited EP 0 685 556 {Ghazarian et al.} and by US 6,368,786 {Saint-Ramon et al.}, these references were/are relied upon for the disclosure of other common ingredients and

common concentrations in common semen extender compositions. The cited EP 0 685 556 {Ghazarian et al.} and by US 6,368,786 {Saint-Ramon et al.} disclose compositions with non-animal derived phospholipid such soy lecithin. And the cited US 6,140,121 {Ellington} suggests incorporation of soy lecithin as alternative to egg yolk for the non-egg yolk containing semen extenders (page 27, lines 20-30).

Unlike applicants' opinion, the cited US 6,140,121 {Ellington} clearly teaches semen extender compositions. It teaches/suggests incorporation of various buffers, surfactants, cryoprotective agents, anti-oxidants including Tris buffer, glycerol, vitamin E and polyoxyethylene sorbitan or Tween 80 (within the culture medium M199) into compositions intended for semen preservation (see starting at col. 16, lines 57-67 to col. 17, lines 1-22). US 6,140,121 also suggests incorporation of soy lecithin into non-egg yolk containing semen extenders (page 27, lines 20-30). The use of medium M199 is taught/suggested as a culture medium not a basic salt solution as presently argued (see col. 16, line 58). It is known that the medium M 199 contains polyoxyethylene sorbitan or Tween 80 as well as antioxidants or vitamins (see ATCC Catalogue, page 522).

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the cited references. Further, they do not show how the amendments avoid such references.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

AU 1651

October 27, 2004

V. Afremova

VERA AFREMOVA

PATENT EXAMINER